

1 A I'm checking that now. It's taking time.
2 They've got cross-outs on here. I mean, this is not a
3 good analytical sheet. The numbers are good. But if I
4 were training an analytical chemist I'd say you don't
5 cross the number out and not put your initials and the
6 date on there. That's what I'm looking at right there.

7 Q Regardless of whether you like Celsis
8 Analytical Labs' methods, did the three samples pass?

9 A It was just distracting to me. But the
10 three samples, samples, passed, yes.

11 Q Okay. Had you ever seen that document
12 before?

13 A No.

14 Q Here's Exhibit 69. Have you ever seen
15 this before?

16 A I'm only on the first page, but my answer
17 is no.

18 Q Okay. I will represent to you that
19 Exhibit 69 represents UDL documents concerning the
20 testing of Digitek Lot 80111A and that it passed the
21 tests to which it was subjected. Am I correct?

22 A This .25 milligram dose, yes, you are
23 correct.

24 Q All right. I'm showing you Exhibit 70.
25 Have you ever seen that before?

1 A I believe I have not seen that before.

2 Q I will represent to you that that's UDL
3 documents about the testing of Digitek Lot 71034A and
4 that the samples passed the test to which they subjected
5 it. Am I correct?

6 MR. KERENSKY: You read 71034A and there
7 appears to be a 1 after the A.

8 MR. MORIARTY: Correct.

9 MR. KERENSKY: You didn't say the 1.

10 Q Okay. Well --

11 A I heard your question. I'm looking up the
12 data to tell you if they did pass. Yes, they do pass.
13 The sample passed.

14 Q I'm handing you Exhibit 71. Have you ever
15 seen it before?

16 A I believe not.

17 Q I will represent to you that Exhibit 71 is
18 the UDL documents concerning their testing of Digitek
19 Batch 71004A1 and that the Digitek passed all the tests
20 to which they subjected it. Am I correct?

21 A Yes. I'm looking at what tests were done.
22 That's why I'm pausing. Yes.

23 Q I'm showing you Exhibit 72. Have you ever
24 seen that document?

25 A I believe I have not.

1 Q I will represent to you that it is UDL's
2 documents regarding the testing of Digitek Lot 70175A1
3 and that the Digitek passed the tests that they -- to
4 which they subjected it. Am I correct?

5 A I'm looking. Yes, you are correct.

6 Q Okay. Now, are you aware that UDL, one of
7 the things that they did was to re-package Digitek from
8 bottles to blister packs?

9 A I was not aware it was UDL who did that.

10 Q But you know it happened at some
11 distributor level?

12 A Yes.

13 Q And do you know for a fact from any
14 documents you've reviewed or any depositions you've read
15 whether tablets that were double their intended
16 thickness would have fit into UDL blister packs for
17 Digitek?

18 A I don't know the answer as to whether they
19 would or would not.

20 Q Would it be important for you to know the
21 answer to that question?

22 A I believe it would certainly be, yes, nice
23 to know.

24 Q Because if UDL never rejected any Digitek
25 tablets as double thick, that would be some scientific

1 information about consistency of the thickness of the
2 product, correct?

3 A It would. I would have to see their
4 records as to whether they rejected any. I would have
5 to see their method of packaging to determine if -- what
6 system they used to reject anything that was too large
7 or too small.

8 Q Do you know whether the UDL thickness
9 specifications for the product were even tighter than
10 the Actavis specifications?

11 A I don't know that.

12 THE VIDEOGRAPHER: It's time to make a
13 tape change, sir.

14 MR. MORIARTY: I'm sorry?

15 THE VIDEOGRAPHER: I have to make a tape
16 change. We are off record at 11:28. Just one
17 moment. Pause, please.

18 (Off the record.)

19 THE VIDEOGRAPHER: All right. We're back
20 on record. This is the beginning of Tape No. 3 in
21 the Farley deposition.

22 BY MR. MORIARTY:

23 Q From your knowledge of the way that FDA
24 looks at things, if UDL re-packaged Digitek from bottles
25 to blister packs, would UDL be required to test for

1 stability on the product in order to assure that the
2 change in packaging didn't change the shelf life of the
3 drug?

4 A If you have a contact surface area of the
5 plastic to use to generate current against there,
6 somebody would be required to test for stability because
7 of the contact with the drug product.

8 Q Have you ever seen any records from UDL
9 regarding the results of stability testing for Digitek?

10 A No.

11 Q When they test for stability do they test
12 for assay typically?

13 A Among others, but that would definitely be
14 it.

15 Q Would they typically do content
16 uniformity? Or I'm sorry. Let me withdraw that.

17 Would they typically also do dissolution?

18 A For tablets would they typically?
19 Usually, not invariably, but most times. Typically was
20 your word. Let's use that. Yes.

21 Q To your knowledge did any Digitek batch
22 ever fail stability under any UDL program?

23 A I don't know the answer to that.

24 Q Would that be important information for
25 you to know?

1 A It would be.

2 Q And if you assume that no Digitek batch
3 ever failed stability under a UDL program, does that
4 speak to the consistency of the quality of the product?

5 A If I saw the stability protocol and if I
6 saw the method they used and agreed that it was a good
7 method and if I knew it was a well-trained person
8 conducting it, everything that would give credibility to
9 the results, then, yes, it would.

10 Q And no one has submitted any of that kind
11 of data to you for review in this litigation, correct?

12 A I believe they did not.

13 Q And you have no reason to believe that FDA
14 has questioned the testing methods of UDL, correct?

15 A Correct.

16 Q If -- have you been supplied any
17 information about testing on Digitek done by NMS Labs
18 from your previous home area of Philadelphia?

19 A No.

20 Q Are you familiar with NMS Labs?

21 A No.

22 Q If anybody ever presented you with testing
23 information about Digitek would you want to look at
24 their methodology and validation before you drew any
25 conclusions about the validity of the testing?

1 A That and more. The reputation of the
2 company, something about the training of the analysts
3 who were running it. Everything you said and more.

4 Q Okay. Now, my colleague, Mr. Anderton,
5 already asked you some questions about the regulatory
6 definition of adulteration. And I don't want to repeat
7 those questions, but I have a follow-up.

8 Have you ever seen any peer reviewed
9 scientific literature, any FDA statements or any other
10 kind of scientific statement which says in words or
11 effect that the regulatory definition of adulteration
12 means that there was out-of-specification product in
13 fact either made or distributed?

14 A You're getting to like within the
15 definition of adulteration? Is that -- am I reading
16 your question properly or am I not?

17 MR. ERNST: Objection to form.

18 Q I thought the question was plain. If you
19 don't understand it I'll be happy to rephrase it.

20 A Okay. Just one more time. Let me see if
21 I get it this time.

22 Q Okay. All right. Let me go back. All
23 right. Mr. Anderton asked you about Exhibit 39. Okay?

24 A I forget what one that is offhand but --

25 Q I'm handing you from the original stack

1 what Exhibit 39 is. Okay?

2 A Yes. I see it.

3 Q And this is the statement from the FDA's
4 own Web site, Facts About Current Good Manufacturing
5 Practices, correct?

6 A It looks like it is.

7 Q And about halfway down there's a bolded
8 question that says, If a manufacturer is not following
9 CGMPs are drug products safe for use.

10 Do you see that?

11 A Yes.

12 Q And then it basically gives the statement
13 that if a company is not complying with CGMPs it makes
14 the drug adulterated under the law.

15 Do you see that?

16 A Yes.

17 Q The last sentence of that paragraph says,
18 It does not mean that there is necessarily something
19 wrong with the drug.

20 Do you see that?

21 A Yes.

22 Q Okay. Now, what I want to know from you
23 is whether you have any peer reviewed literature or an
24 FDA statement or some other scientific statement
25 contrary to what the FDA is saying in its Web site in

1 Exhibit 39.

2 A Stating --

3 Q First a yes or no and then you can
4 explain.

5 A Do I have any evidence of anyone who
6 directly contradicts that?

7 Q That's basically what I was asking you.

8 A I do not.

9 Q Okay. Now, did you want to explain your
10 answer?

11 A Yes.

12 Q Go ahead.

13 A When there's a violation of GMPs it is
14 implied or understood in the industry or generally
15 accepted there is a likelihood that an improper
16 harmful -- potentially harmful product is being released
17 to the public.

18 It, as you say, is not a guarantee, but
19 there's a likelihood that there's a, quote, bad product
20 getting out to the market if in fact it was released.

21 So while there's no direct contradiction here
22 as you asked, it's the general thinking among people in
23 the industry and FDA you didn't comply with GMPs,
24 there's a likelihood of a problem with this material.

25 Q Okay. Let me ask you about that. Does

1 every finding of adulteration lead to a recall?

2 A No.

3 Q Well, if you are correct that there is a
4 likelihood that bad product is out, how come it isn't
5 recalled?

6 A It's a combination of factors. It depends
7 on the product itself. If it's a drug, how sensitive is
8 that drug. In this case it's therapeutic index. A
9 person might get harmed. It's who's taking it. There's
10 a whole variety of factors that go into the
11 determination to do a recall or not.

12 Q But you told me that every time there's an
13 adulteration there's a likelihood that bad product got
14 out. Okay? So where in the FDA rules, regs,
15 interpretations, field manuals does it give this sort of
16 rule that you just said that there's a likelihood but it
17 all depends? Where is it?

18 A In the regulations where it says there's a
19 likelihood?

20 Q Yeah. Where in the regs, where in a piece
21 of scientific peer reviewed literature, where in a
22 manual anywhere that I can go read to check on what you
23 just told me?

24 A It says it's an adulterated product.
25 Since it's an adulterated product it has not been made

1 the way it should have been made and will quite likely,
2 quite likely, not be of the identity, strength, quality
3 and purity they say that it is purported to be and in --
4 it could be harmful.

5 Q Well, does the definition of adulteration
6 in the regulations say that? Does it use the word
7 likely?

8 A I read it somewhere and I'm at a loss to
9 quote it now. I don't know if I read it in the
10 regulations or some document but -- or whether I heard
11 it at meetings at the FDA. I don't know.

12 Q I'm asking you a question of whether the
13 regulation itself that defines adulteration --

14 A Yes.

15 Q -- uses the word likely.

16 A I do not know if it does or doesn't
17 offhand. I would have to read that regulation. I'm not
18 saying it does; I'm not saying it doesn't. I just don't
19 know.

20 Q So let me get back to my basic question.
21 Can you cite for me a piece of peer reviewed literature,
22 a regulation, a manual, any piece of scientific
23 information that indicates that adulteration means that
24 there is a likelihood that bad product actually made it
25 to the market?

1 MR. ERNST: Objection to form.

2 A It means by definition --

3 Q Wait. Answer my question, please, and
4 then you can give your explanation.

5 MR. ERNST: Objection to form. You
6 haven't asked a question.

7 A I thought I was trying to answer your
8 question. Can I try that again to see --

9 Q Sure.

10 A It means you didn't make it the way you
11 said you would make it, and therefore, it is not exactly
12 what you said it would be.

13 Q Isn't it in fact just possible that it's
14 not what you said it would be?

15 MR. ERNST: Objection to form.

16 A The way we would think when I was at FDA,
17 the thinking that's engrained into you is, you didn't
18 make it the way you said, therefore it isn't what you
19 want it to be.

20 Q Okay. I'm asking you, but isn't it just
21 possible that it's not what you want it to be as opposed
22 to likely?

23 MR. ERNST: Objection to form.

24 A Getting into possible, likely, probable,
25 that depends on who you ask.

1 Q I'm asking you under oath today as an
2 expert in the Digitek litigation. Okay? You can't
3 point me to anything in the regs or any other scientific
4 writings that support what you're saying.

5 So I'm asking, isn't it in -- a fact that when
6 there is an adulteration by definition under the FDCA,
7 that it only means it's possible that bad product
8 actually got out?

9 MR. ERNST: Objection to form.

10 A Now, if you're asking me how I would feel
11 about it, if you put a medication in front of me like
12 Lipitor that I take and said this is a -- this is a
13 generic firm made this, but it wasn't made according to
14 GMPs, take it, Jim, and save a few bucks, I would say, I
15 don't want to take that, because in my mind there's a
16 likelihood that something is wrong with that.

17 Q So that's your personal opinion?

18 A That's -- that's the opinion I just gave.
19 I wouldn't take it if someone said this is -- this would
20 save you a couple bucks, but it's not made according to
21 GMPs. I wouldn't.

22 Q Okay. So that's why in your article that
23 we asked you about before you actually want to test it
24 to see if it is or isn't, right?

25 A I would want to test it to see the final

1 product, assay, everything. But I also want to know
2 it's made according to GMPs.

3 Q Well, that's -- anything in Exhibit 39 in
4 the FDA's own Web site that says that it's likely that
5 the product that got out was in fact bad?

6 A I don't see the word likely.

7 MR. ERNST: Form.

8 Q Did your co-author, Mr. Brooks, in your
9 article that you guys wrote cite any law or regulations
10 to say that it's likely that defective product is out
11 there when it's adulterated?

12 A I don't actually remember whether we did
13 or not. I don't. It was over two years ago we wrote
14 that.

15 Q Okay.

16 MR. MORIARTY: Does it smell to anyone
17 else in here like there is something burning?

18 THE VIDEOGRAPHER: Do you want to go off
19 record?

20 MR. MORIARTY: Yeah.

21 THE VIDEOGRAPHER: We're off record. The
22 time is 11:44.

23 (A brief recess was taken.)

24 THE VIDEOGRAPHER: We're back on record,
25 11:44.

1 MR. MORIARTY: Okay. Let's go back on
2 the record.

3 BY MR. MORIARTY:

4 Q Have you ever seen any Actavis documents
5 from either blend uniformity testing or finished product
6 testing that show out-of-specification results for
7 Digitek?

8 A Out-of-specification with regard to double
9 thickness?

10 Q Or normal size, too much API, other than
11 the 20 tablets in 70924.

12 A Other than that?

13 Q Yeah.

14 A I was going to say what I've seen is those
15 documents and I didn't --

16 Q And the assays?

17 A -- see those results on them. I have not
18 seen anything since then.

19 Q Okay. Let's go back to this statement
20 about likelihood or not likelihood. Okay? This goes
21 here. This is Exhibit 38. It's another statement from
22 the FDA's Web site called Facts and Myths About Generic
23 Drugs.

24 A I see it.

25 Q On the second page near the top it says

1 Myth, There are quality problems with generic drug
2 manufacturing. A recent recall of generic Digoxin,
3 called Digitek, shows that generic drugs put patients at
4 risk.

5 And then it says Fact, FDA's aggressive action
6 in this case demonstrates the high standards to which
7 all prescription drugs, generic and brand name, are
8 held.

9 Do you see that?

10 A I do.

11 Q All right. In the fourth bullet point it
12 says, In our best judgment given the very small number
13 of defective tablets that may have reached the market
14 and the lack of reported adverse events before the
15 recall, harm to patients was very unlikely.

16 Do you see that?

17 A The fourth bullet point?

18 Q Yes, sir.

19 A I see it but I'm questioning the FDA
20 putting that on their Web site. I'm not doubting what
21 you put in front of me, but I'm questioning their
22 mentality when they put that out there, because they
23 don't usually get specific.

24 And I think when Mr. Anderton presented this I
25 said the same thing. I said they don't usually go into

1 brand names. And it's very much of a surprise. But,
2 yes, I see what you put in front of me.

3 Q All right. Other than 483s and warning
4 letters what documents have you seen to indicate that it
5 is likely that there was defective Digitek in the hands
6 of any consumer?

7 A Consent decree.

8 Q Anything else?

9 A A consent decree is a big deal. That's a
10 big --

11 Q Can consent decree say -- even have the
12 word Digitek in it?

13 A It essentially said, my words, we don't
14 think you're capable of making anything right;
15 therefore, you need a third party to help you make it.

16 Q Okay. So you've seen all this Celsis Labs
17 testing.

18 A No.

19 Q You've seen the FDA's testing.

20 A This morning.

21 Q And you haven't even looked at any Actavis
22 batch records other than 70924. So other than the FDA's
23 regulatory documents what have you seen to indicate to
24 you that there is any likelihood of out-of-spec Digitek
25 in the hands of any consumer?

1 A It sounds to me like you're minimizing the
2 significance of a 483 or a warning letter.

3 Q No, sir.

4 A They are serious things.

5 Q What I'm trying to ask you -- I'm trying
6 to understand your opinions and the support for your
7 opinions.

8 A Yes.

9 Q I understand what you relied on, those
10 three categories. I want to know if there's anything
11 else. Okay? You've said warning letters, 483s and a
12 consent decree. Anything else?

13 A And the double thick tablets that were
14 found and not analyzed, which is surprising.

15 Q I'm -- maybe you're missing the question.

16 A I might be.

17 Q Okay? I want to know any documents that
18 indicate to you the likelihood that out-of-spec Digitek
19 made it to the hands of consumers, okay, hands of
20 consumers, not rejected at the plant.

21 A Separate from my feeling that there was a
22 good possibility that some might, I haven't seen a
23 document that indicated that there was. But what I'm
24 looking at is not the quantity.

25 You could show me a hundred more analytical

1 results of a bottle here and a bottle there. But when I
2 take the few 483s and couple of warning letters and I
3 look at what was wrong with that place, I realized the
4 sampling was a very small amount. And I would not have
5 confidence in taking any medication that they produced.

6 Q Okay.

7 A So that's a lengthy answer, but I want to
8 put it in a proper perspective for all of us.

9 Q If a client hired you to analyze this, you
10 would look at the actual records, the manufacturing
11 records, the testing records, things of that nature.
12 You would actually want the detail, not just the
13 broadbrush of the 483s, correct?

14 A Including the methods and the training,
15 all of the above.

16 Q All right. Did you review any annual data
17 reviews or annual reports?

18 A I did not. I believe I did not.

19 Q Do you know that has summaries of all of
20 the testing, finished product testing --

21 A Yes.

22 Q -- for every batch?

23 A Yes.

24 Q Now, the ANDA -- you know what that is,
25 right --

1 A It's the Abbreviated New Drug Application
2 for generic.

3 Q -- contains a -- have you seen the ANDA
4 for Digitek?

5 A The actual ANDA?

6 Q Yeah.

7 A No.

8 Q I mean, a copy of it?

9 A No.

10 Q Well, you know that the ANDA has a product
11 formula, does it not?

12 A Yes.

13 Q It lists the ingredients and the amount of
14 an ingredient?

15 A Yes.

16 Q And you know that formula was approved by
17 FDA?

18 A Yes.

19 Q And do you know typically in the
20 manufacturing process that raw materials, including the
21 API, are weighed at the beginning of each batch to
22 assure that the proper amount is put in that complies
23 with the formula?

24 A Yes.

25 Q Do you know that from review of any batch

1 records that when they are blended one person verifies
2 it and it's verified by a second person that the
3 blending is done properly?

4 A Yes. I only reviewed the one batch record
5 and in that one I found that the same person checked his
6 or her own work, which is sacrilegious, one might say.

7 Q In the blend?

8 A In -- somewhere along the way. I forget
9 offhand. I'd have to review the batch record again to
10 answer that. But I found -- in effect I'm saying I
11 found a flaw in it and that flaw was a person checking
12 his or her own work, same initials on the left side and
13 right side of the sheet, which is a violation right
14 there.

15 Q Have you seen any citations, warnings or
16 sanctions from the FDA upon Actavis for not following
17 the Digitek formula that was set out in the ANDA?

18 A No.

19 Q Did Actavis keep raw material inventory
20 cards?

21 A I do not know that. They should. They're
22 supposed to.

23 Q Have you ever seen anything to indicate
24 that Actavis was using Digitek components at rates
25 inconsistent with their batch production?

1 A No. I saw they were not cleaning the
2 materials properly, the equipment, between batches,
3 which cause concern. But your question referred to the
4 proper amounts, I believe, and my answer is no.

5 Q My questions are relatively specific and
6 direct.

7 A Okay.

8 Q If you can just answer mine --

9 A Okay.

10 Q -- not some other. I didn't ask you about
11 cleaning validation or anything else.

12 A Yes.

13 Q I asked about inventory.

14 A Yes.

15 Q Okay? Have you ever seen evidence of an
16 FDA citation, warning or observation that Actavis was
17 using too much Digoxin as tested at the blend uniformity
18 stage?

19 A No.

20 Q Do you know that periodically tablets are
21 tested by QA and production during manufacturing for
22 hardness, thickness and weight?

23 A Yes.

24 Q Do you know that those sampling plans were
25 approved by the FDA?

1 A I didn't see them, but I would have to
2 assume they were.

3 Q Have you ever seen any FDA citation,
4 warning or observation to indicate that Actavis was not
5 following its FDA approved sampling plans?

6 A I'm reflecting on the 483s as I'm
7 formulating my answer. I'm trying to think if sampling
8 plans were in the 483s. My answer is no.

9 Q Do you know how many out-of-specification
10 results occurred of the 270 Digitek batches made between
11 2003 and 2007 during production for weight, thickness or
12 hardness?

13 A I do not know.

14 Q Now, from a manufacturing and quality
15 standpoint is there a difference between a double thick
16 tablet and a normal sized tablet with too much active
17 pharmaceutical ingredient?

18 A Is there a difference?

19 Q Yeah.

20 A The very fact it's double thick is the
21 difference. I need a little more information --

22 Q Sure.

23 A -- on the question. I'm not getting it.

24 Q Well, I know you're not a manufacturing
25 expert. But in fact, is the root cause of a double

1 thick tablet different from the root cause of a normal
2 sized tablet that has too much active pharmaceutical
3 ingredient?

4 A It can be.

5 Q Do you think the FDA knows the difference
6 between a double thick tablet and a normal sized tablet
7 with too much active pharmaceutical ingredient?

8 A They should.

9 Q Did you ever see any citations, warnings
10 or observations to indicate that Actavis was
11 manufacturing Digitek normal size but too much active
12 pharmaceutical ingredient?

13 A I did not see much analytical data at all
14 and I did not see anything to that effect.

15 Q I'm not asking you about analytical data.
16 I'm asking whether you saw any FDA observations,
17 citations or warnings to indicate that Actavis was
18 making Digitek normal size but with too much active
19 pharmaceutical ingredient.

20 A No.

21 Q And the FDA approved recall notice didn't
22 say anything about normal size tablets with too much
23 API, did it?

24 A Correct.

25 Q If FDA was concerned about the specific

1 problem of normal sized tablets with too much API, do
2 you think they would have had Actavis say something
3 about that in the recall notice?

4 MR. ERNST: Objection to form.

5 A I'm thinking whether they would have
6 tested it first or got the recall out first. I believe
7 they would have said something about it, tell the reason
8 for the recall.

9 Q And they probably would have said
10 something about it in Exhibit 38 on their Web site when
11 they specifically talk about Digitek and the recall a
12 year and a quarter after the recall had occurred,
13 correct?

14 A I can't predict what they would or would
15 not because I'm not in agreement with the way they
16 formulated this in the first place.

17 Q Well, if information had come to the FDA's
18 attention even post-recall that there was a problem with
19 normal sized tablets and too much active pharmaceutical
20 ingredient in them, don't you think they would have said
21 something in Exhibit 38 about that?

22 A I don't know. I can't predict what they
23 would or wouldn't put on there. I really can't answer
24 that. I don't know who can.

25 Q Well, if you worked for the FDA wouldn't

1 you say something about that?

2 A I think the answer to that you'd have to
3 ask Dr. Margaret Hanburg. She's the commissioner.

4 Q Were the finished product testing plans
5 approved by FDA?

6 A They should have been.

7 Q Were they in every batch record?

8 A Should have been.

9 Q Did FDA have every opportunity to inspect
10 and comment upon those testing plans between 2004 and
11 2008?

12 A I don't know what the inspectors had on
13 their agendas when they left the office to go and
14 inspect. I can't speak for that. I'd be happy to read
15 the minds of the ladies who did the inspections.

16 Q I'm not asking whether they had it on
17 their agenda, Mr. Farley. I'm asking whether they had
18 the batch records available for review when they did
19 their inspections.

20 A They could request the batch records at
21 any time. So in that regard it would be available for
22 review if they felt they needed the batch records.

23 Q And if they were suspicious about Actavis'
24 finished product testing program do you think it likely
25 that the inspectors would have looked at those?

1 A About Actavis' finished product testing
2 program --

3 Q Yes.

4 A -- is it likely -- we get into this word
5 likely. It is possible they may have.

6 Q No. So you think if FDA was concerned
7 about Actavis' finished product testing that it's only
8 possible they would have looked at batch records?

9 A At that time when that inspection when
10 they're finding deviations, out-of-specification
11 results, things not being documented, they had their
12 hands full with all the other violations.

13 And they might have gone back to the district
14 and said, I need a couple other people to come with me
15 next week. I'm assuming you mean that day are they
16 going to ask for it.

17 Q No. At some point they would have gotten
18 to it, right?

19 A At some point? They may have gotten to it
20 depending on the personnel -- they had their hands full
21 with all of the violations in the first place.

22 Q At some point it's probable they would
23 have gotten to it, right?

24 A Possible.

25 Q Okay. Did FDA ever cite, warn or observe

1 that Actavis was not following its finished product ANDA
2 procedures for Digitek?

3 A ANDA procedures? Could you explain that
4 more?

5 Q The ANDA sets forth the finished product
6 testing procedures, doesn't it?

7 A I didn't hear you say finished product
8 testing. I'm sorry.

9 Q And it's FDA approved, correct?

10 A Yes.

11 Q Did FDA ever cite, warn or observe that
12 Actavis was not following its finished product testing
13 procedures regarding Digitek?

14 A Procedures that Digitek proposed and FDA
15 said, okay, they're good, do it? No, I did not see
16 that.

17 Q When we say finished product testing
18 procedures, we're on the same page. We're talking about
19 assay, dissolution and content uniformity, correct?

20 A From what I've read here this morning,
21 finished product testing is testing on the product as it
22 leaves to go to the next consumer.

23 Q Do you know what kind of testing it is?

24 A I'm sorry. Say again?

25 Q Do you know what kind of testing they do?

1 A From what I read this morning -- I know
2 what they should do normally, but I know more
3 specifically from what you showed me this morning.

4 Q Well, when you read Batch 70924's records
5 did you look at the kind of testing Actavis subjected
6 the product to?

7 A Yes.

8 Q And it was assay, dissolution and content
9 uniformity, correct?

10 A Yes.

11 Q Okay. Did FDA ever cite Actavis or
12 observe that Actavis had out-of-specification stability
13 results for Digitek?

14 A They cited them for not taking samples at
15 the prescribed time that was in their stability
16 protocol. Therefore, they found a flaw in the program.
17 So when you have a flaw in the program and then you say
18 did I have out-of-spec samples, it's a tough one to
19 answer because you aren't taking all the samples you
20 were supposed to take.

21 Q Okay. I'm just asking, did they ever
22 cite, observe or warn Actavis for out-of-specification
23 stability samples? Yes or no?

24 A For out-of-specification stability
25 samples? No.

1 Q Or content uniformity?

2 A No.

3 MR. MORIARTY: How much time on the tape?

4 THE VIDEOGRAPHER: The time on the tape
5 left is 25 minutes.

6 MR. MORIARTY: Okay.

7 BY MR. MORIARTY:

8 Q Let me see if I can put a question to you
9 a different way. You've -- you've seen the 484s.
10 You've seen the Celsis and UDL testing. I want you to
11 assume that the batch records for Digitek show
12 consistent production within the specifications. Okay?

13 A Yes.

14 Q I want you to assume that.

15 A We'll do that.

16 Q All right. Are you -- do you intend to
17 tell a jury that Actavis was in fact producing defective
18 Digitek and it's just sheer coincidence that none of
19 that defective product was discovered by Actavis, FDA,
20 UDL or Celsis?

21 A I do not intend to tell anybody that
22 because I don't know that. I was -- I don't have
23 confidence they're capable of making a quality product
24 even though they got good analytical results on what is
25 an extremely small percentage of sampling.

1 But I can't say they made bad stuff. I say in
2 my mind I believe there's a likelihood, in my mind, a
3 likelihood that there could be bad material on the
4 market.

5 Q Okay.

6 A Can I clarify that more for my own mind,
7 too?

8 Q Now, if you were going to be consulted by
9 a client for that very problem, okay, somebody says we
10 think there was adulterated product, but all the testing
11 that's been done shows that the product is within specs,
12 what would be your next step to figure out whether there
13 was in fact bad product in order to remove the doubts
14 and wonderings?

15 A I would say to them why do you think you
16 made adulterated product?

17 Q That's not what I'm asking you. You've
18 been consulted. Okay?

19 A Right.

20 Q We know the FDA has done these 483s and
21 the warning letters. Okay?

22 A Uh-huh.

23 Q But all the test results show normal
24 Digitek. No one has come and shown you defective
25 Digitek. What would be your next step as a consultant

1 to advise the company about whether there was in fact
2 out-of-specification Digitek out in the market?

3 A I don't think that's the same question you
4 asked me a minute ago.

5 Q Well, I think -- answer the one I just
6 asked you.

7 A The question --

8 Q Answer the one I just asked.

9 A Give it to me again, please.

10 MR. MORIARTY: Read it back, Angela,
11 please.

12 (The record was read back as requested.)

13 A What's the company asking me? I mean,
14 what's -- I'm missing --

15 Q Mr. Farley, is there defective Digitek in
16 the hands of consumers?

17 A Oh, your company.

18 Q Yeah. Not is it adulterated. We want to
19 know, because we've got all these good test results, is
20 there defective Digitek in the hands of consumers? What
21 do you do as a consultant?

22 A I want to review all your procedures,
23 every procedure, your lab testing, your manufacturing.
24 I want to see existing data. But you've just assured me
25 existing data was good.

1 I want to verify that the methods were
2 accurate, validated and that the personnel are trained.
3 And then I want to look -- I want to watch you make a
4 batch. I want to watch you test it.

5 Q Did FDA ever cite, warn or observe that
6 Actavis didn't have validated methods for the production
7 and testing of Digitek?

8 A They said they weren't using certain
9 methods, that methods that were supposed to be used were
10 not being used. Whether they cited for any being not
11 validated, I'm not sure. There may have been. I'm just
12 not sure. But I do know they said you had procedures,
13 you weren't using them.

14 Q Any that specifically involved the actual
15 quality of the end product?

16 A Anything in manufacturing involves quality
17 of the end product. So my answer is yes.

18 Q Okay. So in your mind if somebody put a
19 label on upside down -- which would be a GMP violation,
20 wouldn't it --

21 A Yes.

22 Q -- that is -- that means it's likely that
23 that product is out of specification?

24 A It means you don't know anything about
25 that product. It means what are you going to do about

1 it. You've got to take that product, that big drum or
2 whatever it is, and test it to be sure that what you
3 think it is is really what it is.

4 Q Okay.

5 A You can't --

6 Q Well, it passed finished product testing,
7 Mr. Farley. So are you telling me that in your mind the
8 upside down label means that that product is out of
9 specification?

10 A No. It means they're -- it means you have
11 to look more into it. There's a possibility it may be.
12 Upside down label, you don't know what's there.
13 Whatever the label says, you don't know what's in that
14 drum.

15 So you have to do a tracking of how whatever
16 it is got there, plus you've got to do some more testing
17 here and now before you do anything with that.

18 Q Okay. Did FDA ever cite, warn or observe
19 that Actavis employees were not properly trained in
20 manufacture of Digitek?

21 A I did not read anything to that effect.

22 Q If the -- if Actavis was consistently
23 producing double thick tablets, is it more likely than
24 not that it would have been detected either by
25 pharmacists filling prescriptions, consumers taking

1 prescriptions or UDL when it was packaging the product
2 in blister packs?

3 A Consistently, that's a somewhat vague
4 term. But if you mean daily with batches that go out,
5 it is likely that someone somewhere would have caught
6 it. It's also likely that some people would have
7 ingested it and either died or had some serious medical
8 problems.

9 Q All I'm asking you is whether it's likely
10 it would have been detected and that is the look,
11 correct?

12 A Oh. I was just saying before or after the
13 fact. It's likely it would have been defected. When I
14 don't know.

15 Q All right. Do you know -- do you know how
16 many -- do you know how many Digitek tablets were
17 recalled?

18 A A figure -- or not -- no. 4.8 million,
19 that's a batch. Many, many millions. I don't know the
20 exact number offhand.

21 Q Okay.

22 A Tablets you're talking about?

23 Q Yeah.

24 A Okay. Many, many millions.

25 Q Like 688 million?

1 A That wouldn't surprise me.

2 Q Do you know how many of the recalled
3 batches were .125 versus .250?

4 A Not offhand.

5 Q Do you know what percentage -- do you have
6 an opinion to a probability what percentage of the
7 recalled Digitek was defective by being out of
8 specification low?

9 A Out of specification low?

10 Q Yes.

11 A I do not --

12 MR. ERNST: Objection to form.

13 A -- have any knowledge to that effect.

14 Q Do you have an opinion to a probability?

15 A No.

16 Q Do you have an opinion to a reasonable
17 degree of probability as to what percentage of the
18 recalled Digitek was defective by being out of
19 specification on the high side of the API?

20 MR. ERNST: Objection to form.

21 A No, I don't have an opinion or any
22 knowledge of that.

23 Q If there were out-of-specification Digitek
24 with the API on the high side, above its specifications,
25 do you have any opinion to a probability as to how high

1 those were?

2 MR. ERNST: Objection to form.

3 A If they were out on the high side do I
4 have an opinion how high they would be?

5 Q Yep.

6 A No.

7 Q Do you have an opinion as to how many
8 double thick tablets were released to the marketplace
9 between 2006 and 2008?

10 A I do not.

11 Q Do you have an opinion to a reasonable
12 probability as to how many normal sized tablets with too
13 much API were released to the market?

14 A I do not.

15 Q Given what you have told me so far I
16 assume you have no opinion to a probability as to how
17 many out-of-specification tablets may have made it into
18 a particular patient's prescription vial, whether they
19 got one or whether they got none, whether some people
20 got tend out of thirty.

21 Do you have any opinions to a probability on
22 that?

23 A No opinion as to a probability.

24 MR. MORIARTY: How we doing on time,

25 Bill?

1 THE VIDEOGRAPHER: We have thirteen
2 minutes, sir.

3 MR. MORIARTY: Okay.

4 BY MR. MORIARTY:

5 Q All right. Flipping through notes, some
6 of these I've already asked you, so -- I think you said
7 in your first deposition you said something about
8 somebody dying from Digitek eight to ten years before
9 the recall.

10 Do you know where you got that information?

11 A I mentioned something that I had heard or
12 read that a person had died. And I think it was
13 Mr. Anderton who put it in the proper perspective and
14 mentioned when.

15 The other part of your question was where did
16 I get that. I am not sure. It might have been Pete
17 Miller telling me or in a conversation. But it was
18 something like that.

19 Q Do you have any scientific basis to know
20 whether people taking normal doses of Digoxin can have
21 toxicity and die as a result?

22 A No. That would be more for an M.D. and
23 I'm not a physician.

24 Q And you haven't read the depositions of
25 Dr. Semigran or Ph.D. Nelson from Cincinnati in this

1 litigation?

2 A No, neither of them.

3 Q So you don't know whether that came from
4 an adverse event report that was in your material or
5 some anecdotal piece of information?

6 A I don't know that -- what was in the
7 adverse --

8 Q This thing about somebody dying eight to
9 ten years before.

10 A I don't know.

11 Q Okay. Are you an expert in statistics?

12 A No, I'm not an expert in statistics. I
13 know a little bit, but not an expert.

14 Q Do you know what level of testing of a
15 product would rise to the level of statistical
16 significance or would you defer to a statistician on
17 that?

18 A I would defer to a -- I would have an
19 idea, but I would defer to a statistician to look for
20 the traditional 95 percent probability of this occurring
21 rather than that.

22 Q Okay. Now, this statement about a total
23 failure of the quality systems --

24 A Yes.

25 Q -- if somebody were to assume that there

1 was a total failure and that Actavis could not make
2 Digitek within the specs, that would be an improper
3 assumption, wouldn't it?

4 A I'm trying to think if it's the same that
5 my thoughts are. I wouldn't trust anything they made
6 after seeing that. But to say that a particular bottle
7 is good or bad, I would have no way of knowing.

8 Q Okay.

9 A Did I answer your question?

10 Q Well, not exactly but I'm going to follow
11 up.

12 A Okay.

13 Q If somebody said there was a total failure
14 of the quality system, so we assume that Digitek could
15 not have been made properly, that would be a wrong
16 assumption, wouldn't it?

17 A If somebody said there was a total
18 failure --

19 Q Yes.

20 A -- and --

21 Q And then assumed that Actavis could not
22 make any Digitek properly, they would be wrong, wouldn't
23 they?

24 A Well, if somebody told me there was a
25 total failure I'd say, tell me why you say that, why are

1 you saying a total failure. Then I would want to hear
2 all the various reasons that made them use that term.
3 Then I would pass judgment.

4 Q I'm asking you a simple question. Okay?
5 If somebody said there's a total failure of the quality
6 system and then they assumed that Actavis could not make
7 Digitek within the specs, from what you know and what
8 you've even seen today that would be a wrong assumption,
9 wouldn't it?

10 MR. ERNST: Objection.

11 A On the samples that were tested those
12 samples were good. So it would be an erroneous
13 assumption to say that everything that came out was bad.

14 Q Okay. Thank you. Now, let me make sure I
15 understand something you said in your deposition -- your
16 first session of your deposition. We had 70924 with the
17 20 double thick tablets, correct?

18 A Yes.

19 Q You remember that?

20 A I remember that.

21 Q And I got the impression from what you've
22 said earlier that if somebody showed you the preceding
23 batch and the trailing batch after 70924 and they were
24 fine and within the specs during production and finished
25 product testing, that you would consider something like

1 70924 to be an isolated incident.

2 Do I understand that correctly?

3 A I need more batches. No, no, not just the
4 one before or the one after. Maybe the five or ten
5 before and the five or ten after.

6 Q Okay.

7 A I need more than just what you said to
8 have me look at that I say potentially isolated
9 incident.

10 Q All right. Did you ask for any specific
11 number of preceding or trailing batches in this case?

12 A I believe my words were something to the
13 effect of give me whatever you can get before and after.

14 Q And did you get anything other than 70924?

15 A No, sir.

16 Q So as it stands right now you don't know
17 whether that was an isolated incident. Is that fair?

18 A Whether the findings of the 20 double
19 thick tablets were isolated?

20 Q Yes, sir.

21 A I do not know if that was or was not an
22 isolated incident.

23 MR. MORIARTY: Okay. Let's go off the
24 record. I want to take five minutes with my
25 colleague to see if I am finished and then she can

1 ask questions if she wants.

2 THE VIDEOGRAPHER: All right. Off
3 record, 12:25 p.m.

4 (A brief recess was taken.)

5 THE VIDEOGRAPHER: We're back on record.
6 This is the beginning of Media Unit No. 4 and it
7 is 12:49.

8 BY MR. MORIARTY:

9 Q Okay. Mr. Farley, I just have two things
10 to do. One is housekeeping. Okay? This is
11 Exhibit 74C. It is the latest version of the notice for
12 this deposition. Okay?

13 A Yes.

14 Q The first notice of deposition was marked
15 as an exhibit in your last session. Do you remember
16 that?

17 A Yes.

18 Q The big difference between this one and
19 that one basically says that you are to bring with you
20 all additional documents that you reviewed.

21 A Yes.

22 Q I asked you in the beginning of your
23 deposition whether you had reviewed additional documents
24 and you said you had not; is that correct?

25 A Yes.

1 Q All right. So let me ask you my final
2 question just to make sure that I can understand how you
3 got to a conclusion. Okay?

4 A Yes.

5 Q If somebody concluded, like you, that
6 there was likely out-of-specification product in the
7 marketplace, they could reach that conclusion in one of
8 two ways. Okay? One is to read the regulatory
9 documents and reach that conclusion, right?

10 A The 483s?

11 Q Yes.

12 A Yes.

13 Q And that's the way you reached your
14 conclusion, correct?

15 A Yes.

16 Q Another way would be to read the results
17 of scientific tests or reports that people had measured
18 out-of-specification tablet in the field. That would be
19 a different way to reach that conclusion, correct?

20 A I wouldn't reach the same conclusion.

21 Q I'm not asking whether you reached that
22 conclusion. That would be another way to reach that
23 conclusion if in fact that it occurred, right?

24 A The conclusion that there was a high
25 probability?

1 Q You told me --

2 A They're different things. A sample is a
3 sample, but the --

4 Q Can you listen to the question --

5 A I'm listening.

6 Q -- please? Don't read too much into the
7 question. Okay? You've reached the conclusion that
8 there was likely defective Digitek in the marketplace,
9 right?

10 A Yes.

11 Q You reached that conclusion through the
12 regulatory documents, the 483s, the warning letters and
13 a consent decree, correct?

14 A Yes.

15 Q You did not reach that conclusion by
16 reading reports of scientists who had observed, measured
17 or tested out-of-specification Digitek in the
18 marketplace, correct?

19 A Correct.

20 MR. MORIARTY: Thank you. I'm done.

21 MS. DONAHUE: Are you ready?

22 THE WITNESS: Any time.

23 - - - - -

24 CROSS EXAMINATION

25

1 BY MS. DONAHUE:

2 Q Good afternoon, Mr. Farley.

3 A Yes, ma'am.

4 Q I introduced myself off the record. I'm
5 Alicia Donahue. I'm with Shook, Hardy & Bacon in
6 San Francisco and I represent the Mylan entities, as we
7 call them, Mylan defendants, and UDL Labs in this case.

8 A Yes.

9 Q And one follow-up question to the
10 deposition notice that I wanted to make sure we covered
11 was in regard to that notice and the documents that you
12 were requested to bring with you today pursuant to the
13 second deposition notice, did you bring any new
14 documents today to the deposition that weren't produced
15 by you either physically or by virtue of the thumb drive
16 at your original deposition back in July?

17 A My time log where I log in what day and
18 how many hours I worked for Meghan.

19 Q That's been updated since your last
20 deposition?

21 A It's last week. It just essentially is
22 last week.

23 Q Could we get a copy of that?

24 A Yes. I have it on the thumb drive over
25 there.

1 THE WITNESS: And, Meghan, I gave that to
2 you last night.

3 A I mean -- excuse me. And I gave it to
4 Meghan last night, yes.

5 MS. DONAHUE: Can we just agree, counsel
6 that, you will --

7 A One is a time log and the other is an
8 activity chart that says more what I did and the time
9 log says when I did it so that it tells me I did what I
10 was supposed to do and I know how much time to --

11 Q I appreciate that.

12 A -- how much time.

13 Q Thank you.

14 MS. DONAHUE: So, counsel, are we in
15 agreement we can get a copy of that?

16 MS. CARTER: Yes.

17 MS. DONAHUE: Thank you.

18 BY MS. DONAHUE:

19 Q Okay. And now, very quickly, I believe,
20 Mr. Farley, you in regard -- in response to one of
21 Mr. Moriarty's earlier questions, I believe you
22 testified that the purpose of your report in this case
23 was to provide the opinions that you plan to render at
24 trial in this case; is that correct?

25 A Yes.

1 Q Okay. And I went through your report
2 pretty diligently and I didn't see any mention of any
3 opinions in regard to either the Mylan defendants or UDL
4 Labs.

5 A Yes.

6 Q Nowhere in that report did you opine that
7 Mylan or UDL -- did you opine in any regard on their
8 conduct in regard to distributing Digitek?

9 A Correct.

10 Q And nowhere in that report did you comment
11 in regard to Mylan or UDL's conduct in regard to any
12 testing that any of those entities may have done in
13 regard to Digitek?

14 A Correct.

15 Q As you sit here today, Mr. Farley, do you
16 intend to offer any opinions at the trial of these cases
17 in regard to Mylan or UDL's conduct in relation to its
18 distribution of Digitek?

19 A I do not intend to.

20 MS. DONAHUE: Thank you. That's all the
21 questions I have.

22 - - - - -

23 CROSS EXAMINATION

24 BY MR. KERENSKY:

25 Q Sir, do you have -- excuse me. Sir, do

1 you have an opinion about whether or not it is probable,
2 that being more likely true than not, that Actavis
3 manufactured Digitek tablets that presented an
4 unreasonable risk of serious bodily injury or death to
5 consumers and that those tablets were actually
6 distributed to the consuming public? Do you have an
7 opinion about that based on reasonable probability and
8 that being more likely true than not?

9 MR. MORIARTY: Objection.

10 Q Answer.

11 A I do have an opinion.

12 Q What is that opinion?

13 A It's my opinion -- and it is based on the
14 483s and the warning letters and the consent decree --
15 that in which the entire manufacturing and testing flow
16 is shown to be completely inadequate and not in
17 compliance with regulatory.

18 It is my opinion there's a very high
19 likelihood that there may be what I call bad product out
20 on the market and that consumers have a chance of being
21 seriously injured.

22 MR. KERENSKY: Thank you. No further
23 questions.

24 Any questions from you, Mr. Ernst? Did
25 we start without him? Don?

1 MR. MORIARTY: It' snot my day to watch
2 him.

3 MR. ERNST: Yes, I do. I've got some
4 questions --

5 MR. KERENSKY: Go ahead.

6 MR. ERNST: -- if I can ask him.

7 MR. KERENSKY: Go ahead and ask him.
8 It's your turn.

9 MR. ERNST: All right.

10 - - - - -

11 CROSS EXAMINATION

12 BY MR. ERNST:

13 Q Is it more likely true than untrue that
14 Digitek tablets that presented a danger to consumers,
15 including the risk of injury and death, were
16 manufactured and placed into the stream of commerce by
17 Actavis?

18 MR. MORIARTY: Objection, asked and
19 answered not 120 seconds ago. Go ahead.

20 A In my opinion it is true what you said,
21 yes.

22 Q Is it more likely true than untrue that
23 Actavis failed to provide adequate quality control over
24 the Digitek tablets that it manufactured?

25 A It is more likely true.

1 Q Is it more likely true than not true that
2 out-of-specification Digitek tablets were manufactured
3 and distributed by Actavis?

4 A It is more likely true. I believe that.

5 Q Is it more likely true than untrue or more
6 probably than not that Digitek tablets that presented a
7 danger to consumers, including the risk of death, were
8 actually placed into the stream of commerce and were
9 received by consumers based upon the information and the
10 documentation that you have reviewed to date?

11 A In my opinion it is more likely true.

12 Q Is it your opinion that based upon your
13 training and experience that documents that you have
14 reviewed, all of the reading material that you are aware
15 of to date that Digitek tablets that were manufactured
16 by Actavis presented a risk of harm to consumers?

17 A Yes.

18 Q And is it your opinion that because of
19 this risk of harm to consumers that Digitek tablets were
20 recalled?

21 MR. MORIARTY: Objection.

22 A Say again, please.

23 Q Sure. Is it your opinion and is it more
24 likely true than untrue that based upon the material
25 that you have reviewed that the Digitek tablets were

1 recalled because they presented a danger to consumers,
2 including the risk of death?

3 MR. MORIARTY: Objection.

4 A Yes.

5 MR. ERNST: Thank you. I have nothing
6 else.

7 - - - - -

8 REDIRECT EXAMINATION

9 BY MR. MORIARTY:

10 Q I have a follow-up question for you.

11 A Yes, sir.

12 Q Now, you've heard Mr. Ernst over the
13 telephone ask you some questions. Does his voice sound
14 familiar?

15 A He was on speaker last night in here.

16 Q Okay. Did Mr. Ernst tell you that in his
17 specific case tablets from his client's prescription
18 were tested by NMS Laboratories and found to be within
19 the Digitek specifications?

20 A No.

21 Q Okay. Is that kind of information
22 important to you in rendering opinions in a case like
23 this?

24 A All information such as that is important,
25 some more or less.

1 MR. MORIARTY: Okay. Thank you. That's
2 all I have.

3 MR. KERENSKY: Let's wrap it up. Head
4 for the airport.

5 THE VIDEOGRAPHER: All right. That
6 concludes the deposition of James Farley. It is
7 12:59 p.m this is the end of Media Unit No. 4.
8 Thank you.

9 (Off the record discussion was had.)

10 MR. MORIARTY: As you know from previous
11 deposition experience you have the right, if you
12 wish, to read and sign the transcript when it is
13 prepared and distributed --

14 THE WITNESS: Yes.

15 MR. MORIARTY: -- to make sure that she
16 typed complicated words properly, spelled them,
17 got everything you said, et cetera. Okay?

18 THE WITNESS: Yes.

19 MR. MORIARTY: Or you can waive that
20 right, trusting that she's an excellent court
21 reporter with obvious long-term experience in this
22 and never had to stop us to ask us anything. It's
23 up to you.

24 THE WITNESS: With all due respect to
25 Angela, I would like to read it.

1 MR. MORIARTY: Fine.

2 (The proceedings were concluded at 1:00 p.m.)

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1 CERTIFICATE

2

3 GEORGIA:

4 CHATHAM COUNTY:

5

6 I, Angela S. Garrett, Certified Shorthand
7 Reporter for the State of Georgia, do hereby certify:

8 That the foregoing deposition was taken before
9 me on the date and at the time and location stated on
10 Page 1 of this transcript; that the witness was duly
11 sworn to testify to the truth, the whole truth, and
12 nothing but the truth; that the testimony of the witness
13 and all objections made at the time of the examination
14 were recorded stenographically by me and were thereafter
15 transcribed by computer-aided transcription; that the
16 foregoing deposition, as typed, is a true, accurate, and
17 complete record of the testimony of the witness and of
18 all objections made at the time of the examination.

19 I further certify that I am neither related to
20 nor counsel for any party to the cause pending or
21 interested in the events thereof.

22

23

24

25

1 D I S C L O S U R E

2 Pursuant to Article 8.B. of the Rules and
3 Regulations of the Board of Court Reporting of the
4 Judicial Council of Georgia, I make the following
5 disclosure:

6 I am a Georgia Certified Court Reporter. I was
7 contacted by my office of McKee Court Reporting, Inc.,
8 to provide court reporting services for this deposition.

9 I will not be taking this deposition under any
10 contract that is prohibited by O.C.G.A. 15-14-37(a) and
11 (b).

12 I have no contract/agreement to provide reporting
13 services with any party to the case, any counsel in the
14 case or any reporter or reporting agency from whom a
15 referral might have been made to cover the deposition.

16 I will charge its usual and customary rates to all
17 parties in the case, and a financial discount will not
18 be given to any party to this litigation.

19
20
21
22
23 _____ Date: January 24, 2011

24 Angela S. Garrett
25 RPR, CCR-B2407

James J. Farley

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